DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

September 8, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-60

Carl Koch
President and CEO
Gas Tech, Inc.
1400 Polco St.
Indianapolis, Indiana 46224

Dear Mr. Koch:

During our inspection on August 27-28, 1997, of your Bentley Welding Supply Company medical oxygen repacking operation located in Ashwaubenon, WI, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 210 and 211 (21 CFR 210 and 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your repacked oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to maintain strict control over labeling issued. No actual master label is available to carefully compare incoming labels for identity and conformity.

2. Failure to follow the Quality Assurance Standard Operating Procedure (QA-SOP) relating to the labels on cylinders being checked by the pumper verifying they are in conformance with master labeling. The pumpers are simply assuring there is a readable label on each cylinder and that the labels

are not defaced. Obsolete and outdated labels are not being destroyed as one lot medical oxygen cylinders filled contained at least three different label versions.

3. Failure to follow the QA-SOPs ensuring proper performance of your equipment. The filter element of your [redacted] Oxygen Purity Analyzer is not checked monthly for moisture and dirt. The quarterly calibration of the oxygen settle pressure gauge and the oxygen fill rack gauge has not been done since April 18, 1997.

4. Failure to have a written procedure for the calibration of the vacuum gauge and failure to calibrate the vacuum gauge.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl

xc: Theodore M. Huebbe
Operations Manager
Bentley Welding Supply Co.
885 Parkview Road
Ashwaubenon, WI 54304